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10/781,582	02/17/2004	Jane P. Bearinger	IL-11213	2811

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Lawrence Livermore National Security, LLC
LAWRENCE LIVERMORE NATIONAL LABORATORY
PO BOX 808, L-703
LIVERMORE, CA 94551-0808

EXAMINER	
ANDERSON, GREGORY A	

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Please find below and/or attached an Office communication concerning this application or proceeding.

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/781,582
Filing Date: February 17, 2004
Appellant(s): BEARINGER ET AL.

Eddie E. Scott
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 17 March 2009 appealing from the Office action mailed 09 March 2009.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,549,633	EVANS ET AL	8-1996
6,034,149	BLEYS ET AL	3-2000

5,836,306 DUANE ET AL 11-1998

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

1. Claims 1, 4, 5, 11, 12, 14, 16, 17, 19-21, 25, 31, 32, 34, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al. 5,549,633 in view of Bleys et al. 6,034,149.

Evans et al. discloses an apparatus for closure of an arterial puncture comprising: a closure body 22, the closure body being made of foam formed into a primary shape and compressed into a reduced secondary stable shape and then controllably actuated to that it recovers its primary shape (Figs. 10-12), a delivery catheter 20 adapted to receive the closure body and adapted to deploy the closure body into the physical anomaly, wherein the foam of the closure body in the secondary shape is configured for positioning the closure body within the anomaly (Fig. 10), and wherein the foam is controllably actuated so that it recovers its primary shape with the primary shape being configured to close the anomaly (Fig. 12). Evans et al. further discloses a plunger 28 for controllably actuating the foam and a tube 26. The foam of Evans et al. takes the form of the container it is in, i.e. a tubular shape when it is within the deployment device and a shape conforming to the tissue surrounding the closure body when deployed, and thus has similar shape to that which a flowing fluid would have in the same scenarios. Further, the foam of Evans et al. has a volume larger than the gap in the vascular wall (Fig. 12) when deployed and smaller than the gap (Fig. 9) when being delivered.

However, Evans et al. does not disclose the foam of the closure body being formed from a shape memory polymer having at least one hard segment and one soft segment wherein the hard segment is formed at a temperature above the glass transition temperature and the soft segment is formed at a temperature below the glass transition temperature. Evans et al. further does not disclose transitioning the closure body to its primary shape by changing the temperature above the glass transition temperature in order to close the anomaly.

Bleys et al. discloses shape memory foam comprising polycaprolactone, polyesters, and biodegradable linkages comprising ester (Col. 5 ll. 19-47, Col. 1 ll. 12-15). Bleys et al. further discloses hard and soft segments (Col. 1 ll. 12-31), the hard segments being formed at temperatures above the glass transition temperature, the soft segments being formed at temperatures below the glass transition temperatures. Further Bleys et al. discloses cooling the foam to a temperature below the glass transition temperature while in the smaller volume condition (Col. 1 ll. 32-37). Further Bleys et al. discloses heating the foam to above its glass transition temperature to transition the foam into its primary shape (Col. 1 ll. 32-37). Further, Bleys et al. discloses using shape memory foams in medical applications (Col. 6 ll. 46-56).

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device of Evans et al. by using the shape memory foam of Bleys et al. in order to provide a foam that exhibits good absorption and retention characteristics, good wicking properties, stability, and simplicity of chemicals to ensure

a minimum of leachable substances in contact with the human body as taught by Bleys et al. (Col. 6 ll. 40-51).

2. Claims 6, 13, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al. in view of Bleys et al. and further in view of Duane et al. 5,836,306.

Evans et al. in view of Bleys et al. discloses the invention essentially as claimed as discussed above.

However, Evans et al. in view of Bleys et al. does not disclose a restraint tube for backbleed measurement.

Duane et al. discloses a restraint tube 14 for the measurement and control of backbleed.

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device of Evans et al. in view of Bleys et al. with the restraint tube of Duane et al. in order to provide backbleed control during and after placement of a catheter within a patient's vascular system as taught by Duane et al. (Col. 2 ll. 44-49).

(10) Response to Argument

Appellant argues that Evans reference does not close a physical anomaly that forms a gap in a vascular wall. Examiner disagrees, while the foam of Evans et al. does not close the gap in the vessel, the Evans et al. device clearly does. The suturing aspect of the Evans et al. device pulls the vessel walls together and is subsequently sealed by the insertion of the foam member. Further, the device of Evans et al. is capable of being inserted within the vessel and if so placed would perform in the same manner as if it is placed slightly above the vessel in the overlying tissue as disclosed by

Evans et al. Appellant further argues that the Evans et al. and Bleys et al. references do not disclose all of the limitations of the claims. All of the limitations of the claims have been addressed above. Further, since the Bleys et al. reference clearly discloses its intended use in medical applications (Col. 6 ll. 46-56) there would be reasonable expectation of success in substituting the non memory foam of Evans et al. with the shape memory foam of Bleys et al.. Appellant further argues that no reason for combining the references has been given, and that Examiner has failed to follow proper Examination Guidelines. Examiner disagrees, as indicated in the above rejections, Examiner has shown that it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device of Evans et al. by using the shape memory foam of Bleys et al. in order to provide a foam that exhibits good absorption and retention characteristics, good wicking properties, stability, and simplicity of chemicals to ensure a minimum of leachable substances in contact with the human body as taught by Bleys et al. (Col. 6 ll. 40-51) and that it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device of Evans et al. in view of Bleys et al. with the restraint tube of Duane et al. in order to provide backbleed control during and after placement of a catheter within a patient's vascular system as taught by Duane et al. (Col. 2 ll. 44-49).

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Gregory A Anderson/

Conferees:

/(Jackie) Tan-Uyen T. Ho/

Supervisory Patent Examiner, Art Unit 3773

/Thomas C. Barrett/

Supervisory Patent Examiner, Art Unit 3775